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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/561,639	09/22/2006	Karsten Wassermann	30251/09017	2889
27530 7590 02/04/2009 NELSON MULLINS RILEY & SCARBOROUGH, LLP 1320 MAIN STREET, 17TH FLOOR COLUMBIA, SC 29201				
EXAMINER				
WEBB, WALTER E				
ART UNIT		PAPER NUMBER		
1612				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/561,639

Applicant(s)

WASSERMANN ET AL.

Examiner

WALTER E. WEBB

Art Unit

1612

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 December 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 13-17, 29-31 and 46 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 13-17, 29-31, and 46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Applicants' arguments, filed 12/30/2008, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 102--New

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 15-17 and 30 are rejected under 35 U.S.C. 102(e) as being anticipated by Matsuno et al., (US 2004/0180925, PCT filed Dec. 27, 2001).

Matsuno et al. claim a combination for therapeutic treatment of Type II diabetes of a dipeptidyl peptidase-IV inhibitor and NN-2344, otherwise known as balaglitazone, as per claim 1. (See claim 24 at pg. 75.) Type II diabetes is a condition benefiting from a reduction of plasma glucose levels, as per claim 15.

Since the composition is taught to be administered to patients with Type II diabetes, as per claim 16, it would inherently reduce or decrease plasma glucose levels, as per claims 17 and 30

Claim Rejections - 35 USC § 103

New

1) Claims 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Matsuno et al. (*supra*) as applied to claims 1, 15-17 and 30 above.

Matsuno et al. differs from the instant claims 13 and 14 insofar as it does not teach the composition in two or more separate containers, or a single container.

It would have been obvious to a person having ordinary skill in the art to have placed the composition of Matsuno et al. in two or more separate containers, or a single container. The artisan would have been motivated to use two or more separate containers for administering the each compound at different times or through different routes, e.g. oral and parenteral. The artisan would have been motivated to use a single container to administer the combined drugs simultaneously.

2) Claims 29, 31 and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Matsuno et al. (*supra*) as applied to claims 1, 15-17 and 30 above, and in further view of MacKellar (US 5,614,379).]

Matsuno et al. differs from the instant claims 29, 31 and 46 insofar as it does not teach that the type II diabetes patient is obese.

MacKellar et al. teaches that upper body obesity is the strongest risk factor known for type II diabetes. (See col. 1, lines 20-21.) MacKellar does not teach the composition of claim 1.

It would have been obvious to a person having ordinary skill in the art at the time of applicant's invention to have administered the composition of Matsuno to an obese patient with type II diabetes, since obesity is associated with type II diabetes. The artisan would have been motivated to treat the entire patient population of type II diabetes, which includes obese patients.

Previous

3) Claims 1, 13-17, 29-31, and 46 remain rejected under 35 USC 103(a) as being unpatentable over Lohray et al. (WO 1997/041097) in view of Villhauer (US 6,011,155).

Applicant argues that neither Villhauer or Lohray provide any indication that balaglitazone ad dipeptidyl peptidase-IV inhibitors should be combined for any purpose, and that the Examiner has improperly used the present specification as a blueprint to reconstruct the claimed invention and has failed to establish a *prima facie* case of obviousness. However, a *prima facie* case of obviousness can be made based on a combination of two references, each teaching the same use for their respective compounds. It was stated that the idea of combining them to form a third composition for the same purpose flows logically from their having been individually taught in the prior art. In regard to Applicant's argument of improper reconstruction, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a

reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). In this case, both references are prior art, and the knowledge was not gleaned only from Applicant's disclosure.

Applicant also argues unexpected synergistic results from the combination of balaglitazone and vildagliptin. A declaration under 37 CFR 1.132 by Claus Christiansen was also filed attesting to the results of the data in regard to reduction of fasting plasma triglyceride, and reduction of free plasma fatty acids. There appears to be synergistic effect from the combination of balaglitazone and vildagliptin in regard to reduction of fasting plasma triglyceride, and reduction of free plasma fatty acids. However, Applicant's invention as claimed is not commensurate in scope with these results. To start, Applicant has not claimed a combination of balaglitazone and vildagliptin, and there is no reasonable explanation given to conclude that the results of balaglitazone and vildagliptin would suffice to cover a combination of balaglitazone with any dipeptidyl peptidase-IV inhibitor. Applicant's claims are also drawn to increasing the plasma level VLDL, and reduction of plasma glucose levels. There is no reasonable explanation provided for an increase in VLDL in these data. And, there was no unexpected results from the combination of balaglitazone and vildagliptin in regard to reduction of glucose. Accordingly, the rejection is maintained insofar as applicant's invention as claimed is not commensurate in scope with the results presented.

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Walter E. Webb whose telephone number is (571) 270-3287. The examiner can normally be reached on 8:00am-4:00pm Mon-Fri EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Walter E. Webb
/Walter E Webb/
Examiner, Art Unit 1612

/Frederick Krass/

Supervisory Patent Examiner, Art Unit 1612